

S/N 09/879,665

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT

Applicant: Douglas R. Daum

Serial No.: 09/879,665

Filed: June 12, 2001

Title: CARDIAC RHYTHM MANAGEMENT SYSTEM ADJUSTING RATE  
RESPONSE FACTOR FOR TREATING HYPOTENSION

Examiner: Frances Oropeza

Group Art Unit: 3762

Docket: 279.358US1

APPENDIX

1-35. (Cancelled)

36. (New) A method including:

detecting a thoracic impedance signal associated with a portion of a subject's thorax; and  
providing a therapy to the subject's heart at least in part in response to a baseline portion  
of the detected thoracic impedance below about 0.5 Hz indicating a fluid shift away from the  
thorax, the therapy assisting to shift fluid back toward the thorax, the providing the therapy  
including adjusting a rate response factor defining a relationship between (a) a pacing rate at  
which stimulations are delivered to the subject's heart; and (b) an activity level or respiration  
sensor signal that is correlative to the subject's metabolic need for cardiac output.

37. (New) The method of claim 36, further including attenuating a high frequency  
component of the thoracic impedance signal.

**38. (New)** A method including:

detecting a thoracic impedance signal associated with a portion of a subject's thorax; and  
providing a therapy to the subject's heart at least in part in response to the detected thoracic impedance, including increasing a rate of pacing stimuli at least in part in response to an increase in the baseline portion of the thoracic impedance below about 0.5 Hz indicating a fluid shift away from the thorax, the therapy assisting to shift fluid back toward the thorax, the providing the therapy including adjusting a rate response factor defining a relationship between (a) a pacing rate at which stimulations are delivered to the subject's heart; and (b) an activity level or respiration sensor signal that is correlative to the subject's metabolic need for cardiac output.

**39. (New)** The method of claim **38**, further including detecting a motion of the subject and providing the therapy to the subject's heart based at least in part on the detected motion of the subject.

**40. (New)** The method of claim **38**, further including detecting a breathing of the subject and providing the therapy to the subject's heart based at least in part on the detected breathing.

**41. (New)** The method of claim **40**, in which providing the therapy to the subject's heart includes adjusting a rate of delivery of pacing stimuli based on frequency components of the thoracic impedance associated with fluid shift away from the thorax and associated with the subject's breathing.

42. (New) The method of claim 38, in which the adjusting the rate response factor includes increasing the rate response factor, in response to the detecting the condition correlative to hypotension, such that a particular sensor indication of metabolic need results in a higher pacing rate after the increasing the rate response factor as compared to before the increasing the rate response factor. ~~providing the therapy to the subject's heart includes providing a therapy from the group consisting essentially of:~~

- ~~—— (a) ——— increasing the subject's heart rate to a predetermined fixed value in response to an increase in detected thoracic impedance at a frequency associated with a fluid shift away from the thorax;~~
- ~~—— (b) ——— increasing the subject's heart rate by a predetermined fixed value in response to an increase in detected thoracic impedance at a frequency associated with a fluid shift away from the thorax;~~
- ~~—— (c) ——— adjusting an applied energy for modifying a heart rate or contractility in response to an increase in detected thoracic impedance at a frequency associated with a fluid shift away from the thorax; and~~
- ~~—— (d) ——— providing a drug to the subject in response to an increase in detected thoracic impedance at a frequency associated with fluid shift away from the thorax.~~

**43. (New)** A method including:

detecting a change in a thoracic impedance signal associated with a subject's thorax and including a thoracic fluid shift signal having a frequency component that is less than or equal to a cutoff frequency value that is between 0.01 Hz and 0.5 Hz inclusive; and increasing a rate of delivery of pacing stimuli at least in part in response to a detected increase in a baseline portion of the thoracic impedance signal indicating a fluid shift away from the thorax, the therapy assisting to shift fluid back toward the thorax and thereby decreasing the baseline portion of the thoracic impedance signal, the increasing the rate of delivery of pacing stimuli , the providing the therapy including adjusting a rate response factor defining a relationship between (a) a pacing rate at which stimulations are delivered to the subject's heart; and (b) an activity level or respiration sensor signal that is correlative to the subject's metabolic need for cardiac output.

**44. (New)** The method of claim 43, in which the cutoff frequency value is approximately 0.1 Hz.

**45. (New)** The method of claim 43, further including detecting a motion of the subject and in which increasing the rate of delivery of pacing stimuli includes also basing the increase on the detected motion of the subject.

**46. (New)** The method of claim 43, in which increasing the rate of delivery of pacing stimuli includes also basing the increase on a frequency component of the thoracic impedance associated with the subject's breathing.

**47. (New)** A method including:

detecting, using an implantable medical device to indicate thoracic hypotension resulting from a fluid shift away from the thorax using transthoracic impedance below about 0.5 Hz to indicate how much fluid is present in a thorax, both a hypotension associated with a change in a subject's posture and a hypotension that is not associated with a change in the subject's posture; and

providing a therapy to the subject's heart at least in part in response to the detected hypotension, the therapy assisting to shift fluid back toward the thorax to reduce the hypotension, the providing the therapy including adjusting a rate response factor defining a relationship between (a) a pacing rate at which stimulations are delivered to the subject's heart; and (b) an activity level or respiration sensor signal that is correlative to the subject's metabolic need for cardiac output.

**48. (New)** The method of claim 47, in which providing the therapy includes increasing a heart rate in response to the detected hypotension.

**49. (New)** A cardiac rhythm management system, including:

first and second electrodes configured for association with a portion of a subject's thorax; a thoracic signal detection module, coupled to the first and second electrodes for receiving a thoracic impedance signal and including an averager/lowpass filter that obtains a baseline portion of the thoracic impedance signal below about 0.5 Hz that is associated with a fluid shift away from the thorax; and

means for performing a function of providing therapy to the subject's heart based on the baseline portion of the thoracic impedance signal, the therapy assisting to shift fluid back toward the thorax, the providing the therapy including adjusting a rate response factor defining a relationship between (a) a pacing rate at which stimulations are delivered to the subject's heart; and (b) an activity level or respiration sensor signal that is correlative to the subject's metabolic need for cardiac output.

**50. (New)** A cardiac rhythm management system, including:

first and second electrodes configured for association with a portion of a subject's thorax;  
a thoracic signal detection module, coupled to the first and second electrodes for receiving a thoracic impedance signal and including an averager/lowpass filter that obtains a baseline portion of the thoracic impedance signal below about 0.5 Hz that is associated with a fluid shift away from the thorax; and

a pacing therapy output circuit providing therapy to the subject's heart in response to the baseline portion of the thoracic impedance signal indicating a fluid shift away from the thorax, the therapy assisting to shift fluid back toward the thorax, the therapy including adjusting a rate response factor defining a relationship between (a) a pacing rate at which stimulations are delivered to the subject's heart; and (b) an activity level or respiration sensor signal that is correlative to the subject's metabolic need for cardiac output.

**51. (New)** A cardiac rhythm management system, including:

first and second electrodes configured for association with a portion of a subject's thorax;  
means, coupled to the first and second electrodes for receiving a thoracic impedance signal, for performing the function of obtaining a baseline portion of the thoracic impedance signal below about 0.5 Hz that is associated with a fluid shift away from the thorax; and  
a pacing therapy output circuit providing therapy to the subject's heart in response to the baseline portion of the thoracic impedance signal indicating a fluid shift away from the thorax, the therapy assisting to shift fluid back toward the thorax, therapy including adjusting a rate response factor defining a relationship between (a) a pacing rate at which stimulations are delivered to the subject's heart; and (b) an activity level or respiration sensor signal that is correlative to the subject's metabolic need for cardiac output.

**52. (New)** A cardiac rhythm management system, including:

first and second electrodes configured for association with a portion of a subject's thorax;  
a thoracic signal detection module, coupled to the first and second electrodes;  
third and fourth electrodes configured for association with a portion of a subject's heart;  
a pacing therapy output module, coupled to the third and fourth electrodes; and  
a pacing stimuli rate controller, coupled to the thoracic signal detection module for receiving a thoracic impedance signal including a baseline signal component associated with a fluid shift away from the thorax, the controller also coupled to the pacing therapy output module for adjusting the rate of delivery of pacing stimuli at least in part in response to the portion of the thoracic impedance signal below about 0.5 Hz associated with the thoracic fluid shift away from the thorax, the adjusting the rate of delivery of pacing stimuli assisting to shift fluid back toward the thorax, the providing the therapy including adjusting a rate response factor defining a relationship between (a) a pacing rate at which stimulations are delivered to the subject's heart; and (b) an activity level or respiration sensor signal that is correlative to the subject's metabolic need for cardiac output.

**53. (New)** The system of claim **52**, in which at least one of the third and fourth electrodes is the same electrode as one of the first and second electrodes.

**54. (New)** The system of claim **52**, further including a thoracic test signal generator configured for association with the thorax for providing energy to the thorax for detecting thoracic impedance.

**55. (New)** The system of claim **52**, in which the rate controller further includes a lowpass filter coupled to the thoracic signal detection module.

**56. (New)** The system of claim **55**, in which the lowpass filter obtains the baseline portion of the thoracic impedance signal that is associated with a fluid shift away from the heart.

- 57. (New)** The system of claim **56**, in which the lowpass filter attenuates a breathing portion of the thoracic impedance signal.
- 58. (New)** The system of claim **56**, in which the lowpass filter attenuates a cardiac stroke portion of the thoracic impedance signal.
- 59. (New)** The system of claim **55**, in which the lowpass filter attenuates a component of the thoracic impedance not associated with the thoracic fluid shift.
- 60. (New)** The system of claim **55**, in which the lowpass filter includes an effective cutoff frequency that is between 0.01 Hz and 0.5 Hz.
- 61. (New)** The system of claim **60**, in which the lowpass filter includes a cutoff frequency that is approximately equal to 0.1 Hz.
- 62. (New)** The system of claim **52**, in which the controller includes a blending module for adjusting the rate of delivering pacing stimuli based on thoracic fluid shift and at least one of:
- (a) a breathing by the subject; and
  - (b) a motion of the subject.



**63. (New)** A cardiac rhythm management system, including:

first and second electrodes configured for association with a portion of a subject's thorax;  
a thoracic signal detection module, coupled to the first and second electrodes;  
thoracic test signal generator configured for association with the thorax for providing energy to the thorax for detecting thoracic impedance;  
third and fourth electrodes configured for association with a portion of a subject's heart;  
a pacing therapy output module, coupled to the third and fourth electrodes; and  
a pacing stimuli rate control module, coupled to the thoracic signal detection module for receiving a thoracic impedance signal, the rate control module including a lowpass filter for distinguishing a baseline thoracic fluid shift signal below about 0.5 Hz from another variation in thoracic impedance, the rate control module also coupled to the pacing therapy output module for adjusting the rate of delivery of pacing stimuli at least in part in response to the thoracic fluid shift signal indicating a fluid shift away from the thorax, the adjusting the rate of delivery of pacing stimuli assisting to shift fluid back toward the thorax, the adjusting the rate of delivery including adjusting a rate response factor defining a relationship between (a) a pacing rate at which stimulations are delivered to the subject's heart; and (b) an activity level or respiration sensor signal that is correlative to the subject's metabolic need for cardiac output.

64. (New) A cardiac rhythm management system, including:  
means for detecting a thoracic impedance;  
first and second electrodes, configured for association with a portion of a subject's heart;  
a pacing therapy output module, coupled to the first and second electrodes; and  
a pacing stimuli rate control module, coupled to the means for detecting thoracic impedance and the pacing therapy output module, the rate control module adjusting a rate of delivery of pacing stimuli at least in part in response to a baseline portion of the thoracic impedance below about 0.5 Hz indicating a thoracic fluid shift away from the thorax, the adjusting the rate of delivery of pacing stimuli assisting to shift fluid back toward the thorax, the adjusting the rate of delivery including adjusting a rate response factor defining a relationship between (a) a pacing rate at which stimulations are delivered to the subject's heart; and (b) an activity level or respiration sensor signal that is correlative to the subject's metabolic need for cardiac output.

65. (New) The method of claim 38, further including attenuating a high frequency component of the thoracic impedance signal.

66. (New) The method of claim 38, further including detecting a motion of the subject and providing the therapy to the subject's heart based at least in part on the detected motion of the subject.

67. (New) The method of claim 38, further including detecting a breathing of the subject and providing the therapy to the subject's heart based at least in part on the detected breathing.

68. (New) The method of claim 67, in which providing the therapy to the subject's heart includes adjusting a rate of delivery of pacing stimuli based on frequency components of the thoracic impedance associated with fluid shift away from the thorax and associated with the subject's breathing.

69. (New) The method of claim 38, in which providing the therapy to the subject's heart includes increasing the rate response factor, in response to the detecting the condition correlative to hypotension, such that a particular sensor indication of metabolic need results in a higher pacing rate after the increasing the rate response factor as compared to before the increasing the rate response factor. ~~providing a therapy from the group consisting essentially of:~~

- ~~—— (a) —— increasing the subject's heart rate to a predetermined fixed value in response to an increase in detected thoracic impedance at a frequency associated with a fluid shift away from the thorax;~~
- ~~—— (b) —— increasing the subject's heart rate by a predetermined fixed value in response to an increase in detected thoracic impedance at a frequency associated with a fluid shift away from the thorax;~~
- ~~—— (c) —— adjusting an applied energy for modifying a heart rate or contractility in response to an increase in detected thoracic impedance at a frequency associated with a fluid shift away from the thorax; and~~
- ~~(d) providing a drug to the subject in response to an increase in detected thoracic impedance at a frequency associated with fluid shift away from the thorax.~~